

STERIS: Certificate Of Processing

Prepared for STIRILAB

Ethylene Oxide Run ID 2002-2116

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202401458	18

Product meets Customer specifications; zero nonconformities occurred during this run.

Other Information

Sterilization Batch Number 22A240321

Customer Specification ID: 37

Signature Manifest

Reviewed and E-Signed By: **Sarka Mejzlikova (Quality Analyst)**

Date/Time E-Signed: 22-Mar-2024 7:57 AM

Document Content Revision: 1

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11135.

This Certificate becomes valid only with the Process Run Record Summary and Biological Indicators Incubation Certificate referring to applicable sterilization Batch Number.

Processing Location

STERIS AST CZ s.r.o.
Průmyslová zóna Košíkov 80
Velká Bíteš
595 01

*** End of Ethylene Oxide Certificate of Processing Document ***

Process Run Record

Summary

STERIS AST CZ s.r.o.
Průmyslová zóna Košíkov 80
595 01 Velká Bíteš, Czech Republic
Tel: +420566562145
Fax:

Run ID:	312091	Pallet Count:	18	Batch No.:	22A240321
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	5998	Method:	STIRILAB 03 EQ-15%
Specification:	1.0				

1. Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	20.03.2024 19:22:18	Date Completed:	21.03.2024 7:09:37
		Duration:	11:47:19

1.1. Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:47:19	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:30:01	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	47,6 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,8 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	54,7 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	65,3 %	45,0 - 95,0 %	✓

1.2. Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:12:40	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	20.03.2024 19:22:18	21.03.2024 7:22:17	11:47:19

Process Run Record Summary

Run ID 312091

2.Vessel Processing

Equipment: **VB Chamber 22** Config. Rev.: **3**
 Date Started: **21.03.2024 7:22:17** Date Completed: **21.03.2024 17:47:13** Duration: **10:24:56**

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	48,6 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	48,6 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:31	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:31	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	12,0 - 32,0 kPa	✓

2.3.Leak Check

Phase No. 3

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:05:01	00:01:00 - 00:20:00	✓
Total Phase Time	Final - P11	00:05:01	00:01:00 - 00:20:00	✓
TE-CH-Lo	Min - P3	49,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	22,0 kPa	12,0 - 33,0 kPa	✓
PCurr	Max - P14	22,7 kPa	12,0 - 33,0 kPa	✓

2.4.Vacuum

Phase No. 4

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:22	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:22	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	21,0 - 22,2 kPa	✓

2.5.Steam Inject by Pressure

Phase No. 5

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:02:03	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:02:03	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	50,1 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record **Summary**

Run ID 312091

Stage » Vessel Processing**2.6. Conditioning Dwell by Pressure**

Phase No. 6

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:25:01	01:10:00 - 01:40:00	✓
Total Phase Time	Final - P11	01:25:01	01:10:00 - 01:40:00	✓
TE-CH-Lo	Min - P3	50,2 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	23,0 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,7 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	59,6 %	N/A - N/A %	
RH Reported	Max - P22	82,8 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:44	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:44	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,8 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	21,0 - 22,2 kPa	✓

2.8. EO Inject by Pressure

Phase No. 8

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:04:12	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:04:12	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,7 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,7 °C	46,0 - 54,0 °C	✓
PCurr	Final - P1028	215,0 kPa	n/a - N/A kPa	
PCurr	Final - P14	215,0 kPa	200,0 - 225,0 kPa	✓
EO Conc. Reported	Final - P33	421,6 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	473,0 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 312091

Stage » Vessel Processing

2.9. Super-Atmospheric EO Dwell

Phase No. 9

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	06:00:01	05:55:00 - 07:00:00	✓
Total Phase Time	Final - P11	06:00:01	05:55:00 - 07:00:00	✓
TE-CH-Lo	Min - P3	49,8 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,2 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,6 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,6 kPa	N/A - N/A kPa	
PCurr	Max - P1028	215,0 kPa	N/A - N/A kPa	
PCurr	Max - P14	215,0 kPa	200,0 - 225,0 kPa	✓
RH Reported	Min - P22	0,0 %	N/A - N/A %	
RH Reported	Max - P22	0,0 %	N/A - N/A %	
EO Conc. Reported	Min - P33	301,8 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	421,6 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	473,0 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	475,0 mg/l	N/A - N/A mg/l	

2.10. Vacuum

Phase No. 10

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:22:51	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:22:51	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	26,0 kPa	16,0 - 36,0 kPa	✓

2.11. Air Inbleed

Phase No. 11

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:24	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:24	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,6 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.12. Vacuum

Phase No. 12

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,6 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 312091

Stage » Vessel Processing**2.13. Air Inbleed**

Phase No. 13

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:17	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:17	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.14. Vacuum

Phase No. 14

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:06	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:06	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

2.15. Air Inbleed

Phase No. 15

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:17	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:17	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,9 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.16. Vacuum

Phase No. 16

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:07	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:07	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	49,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,9 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

2.17. Air Inbleed

Phase No. 17

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	52,1 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Process Run Record Summary

Run ID 312091

Stage » Vessel Processing**2.18.End Phase**

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:05:28	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:05:28	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	52,1 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	93,1 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	21.03.2024 7:22:17	21.03.2024 17:47:13	10:24:56

CONFORMING**Krezek, Ales**

Digitally signed by
Krezek, Ales
Date: 2024.03.22
07:44:47 +01'00'

All dates are expressed in the timezone:

(UTC+01:00) Praha, Bratislava, Budapešť, E

✓ = Pass ✗ = Fail



STERIS

STERIS AST CZ s.r.o.

Laboratories

Registered office: Průmyslová zóna Košíkov 80, 595 01 Velká Bíteš, Czech republic
lab_astercz@steris.com - www.steris-labs.com

Komu: / To **STIRILAB S.R.O.**
TEXTILNÁ 23
03401 RUZOMBEROK SLOVENSKÁ REPUBLIKA

ANALYSIS CERTIFICATE #1938 - BI594 - 03/29/2024

ČÍSLO CERTIFIKÁTU ANALÝZY 1938 - BI594 - 29/03/2024

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Strana 1 / 1

Our Laboratory Reference Register # BI / 193 - p. 124

Evidenční číslo: BI / 193 - s. 124

TITLE: BIOLOGICAL INDICATORS - SPORE STRIP - BACILLUS ATROPHAEUS (B. subtilis var Niger) ATCC #9372

NÁZEV: BIOLOGICKÝ INDIKÁTOR - SPORE STRIP - BACILLUS ATROPHAEUS (B. Subtilis var Niger) ATCC #9372

METHOD: ISO 11138-1

METODA: ISO 11138-1

INTERNAL PROCEDURES: LWI-LAB002

VNITŘNÍ PROCEDURA: LWI-LAB002

REFERENCE DATA

REFERENČNÍ ÚDAJE

SAMPLES DESCRIPTION: ZDRAVOTNICKÉ PROSTŘEDKY - IN VITRO DIAGNOSTIKA

POPIS VZORKŮ: ZDRAVOTNICKÉ PROSTŘEDKY - IN VITRO DIAGNOSTIKA

REFERENCE: STIRILAB S.R.O.

JMÉNO ZÁKAZNÍKA: STIRILAB S.R.O.

WITHDRAWING MADE BY: STERIS

ODPOVĚDNOST ZA VÝBĚR VZORKŮ: STERIS

RECEIVED BY LABORATORY AT: 03/22/2024

DODÁNO DO LABORATOŘE: 22/03/2024

PRODUCTION BATCH: BILL OF DELIVERY: 202401458

PRODUKČNÍ ŠARŽE: BILL OF DELIVERY: 202401458

STERILIZATION BATCH: 22A240321 dtd 03/21/2024

STERILIZAČNÍ ŠARŽE: 22A240321 dne 21/03/2024

BI BATCH: BATR 485

BI ŠARŽE: BATR 485

POPULATION (ufc/strip): $3.7 \cdot 10^6$

POPULACE (cfu / strip): $3.7 \cdot 10^6$

D-value (min): 2.8

D - hodnota (min): 2.8

ANALYSIS PARAMETERS

PARAMETRY ANALÝZY

POSITIVE CONTROLS N: 1

POČET POZITIVNÍCH KONTROL: 1

BIOLOGICAL INDICATORS N: 28

POČET BIOLOGICKÝCH INDIKÁTORŮ: 28

GROWTH EVIDENCE AT THE END OF INCUBATION PERIOD

EVIDENCE RŮSTU NA KONCI INKUBAČNÍ DOBY

BI SAMPLES AFTER 7 DAYS

BI PO SEDMI DNECH

POSITIVE CONTROL BI

POZITIVNÍ KONTROLA BI

negative

negativní

positive

pozitivní

Conclusions

Závěry

EFFECTIVE STERILIZATION CYCLE

ÚČINNÝ STERILIZAČNÍ CYKLUS

LABORATORY RESPONSIBLE
ODPOVĚDNÁ OSOBA

ast 29-03-2024

RELEASED BY QUALITY

Jana Zichová

29-03-2024

Zichová



Transport Document

202401458

STIRILAB s.r.o. a dominique Dutscher company

Textilná 23
034 01
Ružomberok

VAT No. SK2021729545

Tel +421 44 432 27 20 Fax +421 44 432 27 17
www.stirilab.com, email ekonom@stirilab.com

IBAN : SK 311111 000000 102498 0028. SWIFT : UNCRSKBX

CUSTOMER

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

595 01 Velká Bíteš, ČR

SHIP TO

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

59501 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	20.03.2024	202401458		1 to 1

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	30,00
order	lotto 24P2004302	exp 29.02.2028		
BSC740	Fertility collector	40	40,000	34,00
order	lotto 24P2004303	exp 31.03.2028		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	600,00
order	lotto 24P2003401	exp 31.01.2028		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	200,00
order	lotto 24P2003402	exp 29.02.2028		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	500,00
order	lotto 24P2003002	exp 29.02.2028		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 500,00
order	lotto 24P2003003	exp 31.03.2028		

ACCEPTANCE VERIFICATION

SHIPPING BY

EXW

ISSUED BY:

Bošeková

TRANSPORT

SALE

TRANSPORT START DATE

20.03.2024

DELIVERY TERM

EXW

BOXES

344

PALLETS

18

GROSS WEIGHT KG

2 714,21

NETTO WEIGHT

2 465,06

VOLUME m3

20,34

DRIVER'S SIGNATURE

ANNOTATIONS

RECIPIENT'S SIGNATURE

Any complaint must be made within 8 days after goods receipt. Goods are considered of customer property only after full payment receipt. Any disputes between the are subject to the exclusive jurisdiction of the courts of Slovak republic